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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/306,006 05/06/99 SUPERSAXO A NB/2-21551/A

000324 HM12/0705  
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PATENT DEPARTMENT  
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EXAMINER

SHARAREH, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

07/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/306,006

Applicant(s)

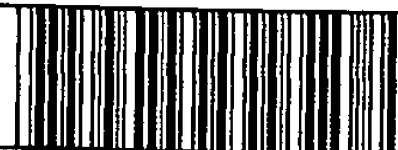
Supersaxo et al

Examiner

Shahnam Sharareh

Group Art Unit

1616



☒ Responsive to communication(s) filed on Apr 10, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 2, 5, 6, 9, 10, 15-21, 24, 28, and 29 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 2, 5, 6, 9, 10, 15-21, and 24-29 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

Amendment filed on April 10, 2000 has been entered. Accordingly, claims 1, 3-4, 7-8, 11-14, 22-23, 25-27 have been canceled, and claims 28-29 have been added. Claims 2, 5-6, 9-10, 15-21, 24, 28-29 are now pending.

#### *Response to Amendment*

1. Applicant's arguments filed on April 10, 2000 in respect to the rejection made 1-27 rejected under 35 U.S.C. 112, first paragraph have been fully considered, but are <sup>is</sup> ~~not~~ found persuasive in view of the amendments to the claims.
2. Applicant's amendments to the claims filed on April 10, 2000 has obviated the rejections made under 35 U.S.C. 112, second paragraph, as being indefinite for particularly pointing out the subject matter which applicant regards as the invention. Said rejections are withdrawn. The pending claims are now definite.
3. Applicant's arguments filed on April 10, 2000 in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Mizushima et al U.S. Patent 5,171,566 have been fully considered and are partially found persuasive in respect to the method claims. However, claims 16-17, 20-21, 29 are still rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Mizushima et al U.S. Patent 5,171,566.

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Applicant argues that Mizushima et al do not teach the instant step (c ). In response, Examiner states that the instant compositions appear to be drafted as "product by process" claims.

Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.)

"Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985).

The instant claims are directed to methods of preparing a composition comprising mixing a membrane forming molecule, a coemulsifer and a lipophilic component with a pharmaceutical agent. The instant claims are also directed to nanodispersion compositions comprising a membrane-forming molecule, coemulsifier, and a lipophilic component.

Mizushima et al disclose an ophthalmic preparation which can be prepared in the form of a fat emulsion comprising soybean oil (lipophilic component), a phospholipid (a membrane forming molecule), and various stabilizers such as polyoxyethylene-polyoxypropylene copolymers, and active agent such as flurbiprofen (see col 3 lines 1-35, examples 1-3), thus, Mizushima et al meet the limitations set forth in the instant claims.

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5. Applicant's arguments filed on April 10, 2000 in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Nakajima et al US Patent 5,338,761 have been fully considered and are not found persuasive. The instant rejection is now applied to claim 29.

Applicant argues that Nakajima et al do not teach the instant step (c ). Examiner replies that as stated above the instant compositions appear to be drafted as "product by process" claims. Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.)

"Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985).

6. Applicant's arguments filed on April 10, 2000 in respect to the rejection made under 35 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Owen et al US Patent 5,633,226. and are not found persuasive. The instant rejection is now applied to claims 2, 5-6, 9-10, 15-21, 24, 28-29 in view of cancellation of claims 1, 3-4, 7-8, 11-14, 22-23, 25-27.

Applicant argues that said Owen's compositions are directed to water soluble biologically active material in contrast to the instant compositions that comprise only lipophilic components as component (c ). This argument is not persuasive because Owen's composition are directed to

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suitable pharmaceutically active material (see claim 10) and that can be determined by one ordinary skilled in the art to be a suitable lipophilic or hydrophilic agent. Secondly, the policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components essential to the operability of the cited prior art patents. Thirdly, the instant composition claims are drafted as "product by process" claims. Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.) Thus, claims 2, 5-6, 9-10, 15-21, 24, 28-29 are still rejected.

*New Grounds of Rejection*

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. <sup>2, 5-6, 9-10, 15-21, 24-29 (92)</sup> Claims rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/16441 .

The instant claims are directed to methods of preparing a composition comprising mixing a membrane forming molecule, a coemulsifer and a lipophilic component with a pharmaceutical agent. The instant claims are also directed to nanodispersion compositions comprising a membrane-forming molecule, coemulsifier, and a lipophilic component.

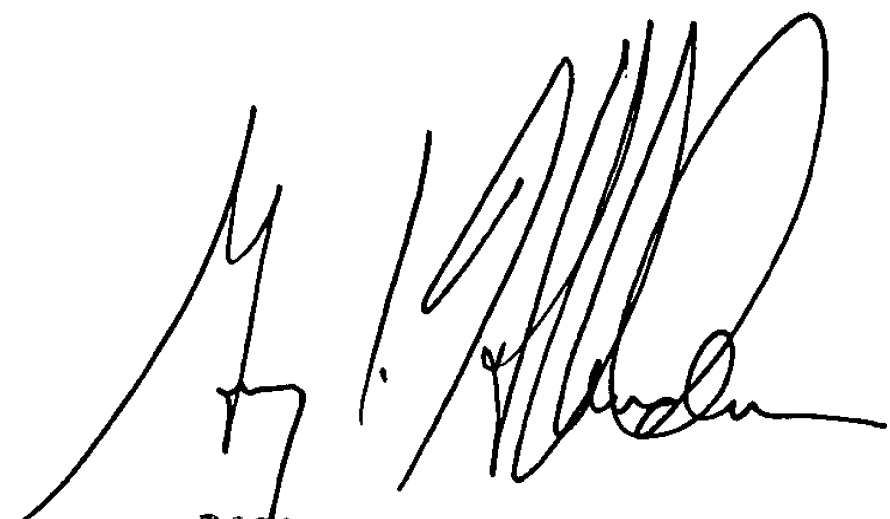
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WO 95/16441 disclose compositions ultramicroemulsions which converts to an oil in water emulsion comprising a bioactive agent, an oil dispersible surfactant comprising a membrane forming material such as phospholipids with other surfactant, a pharmaceutically acceptable oil, an aqueous phase such as ethanol (see example 14-16, and claims 1-3.) Accordingly WO 95/16441 meet the limitations set forth in the instant claims.

*Conclusion*

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjs, 7/2/2000*



GARY E. HOLLINDEN, PH.D.  
PRIMARY EXAMINER  
GROUP 1200